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Does counselling benefit post-myocardial infarct patients in reducing anxiety/depression and enable them to make positive life style changes in comparison to a non-counselled group?

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 21/04/2015	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0388170251

Study information

Scientific Title
Does counselling benefit post-myocardial infarct patients in reducing anxiety/depression and enable them to make positive life style changes in comparison to a non-counselled group?

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular: Infarction

Interventions
Counselling vs non counselling

Intervention Type
Behavioural

Primary outcome measure
1. Improve quality of life of myocardial infarct patients
2. Comparison of HAD scores (Hospital Anxiety & Depression scale) at six-eight weeks post-discharge and 6 months
3. The CORE (Clinical Outcome Routine Evaluation) will also be used

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2004

Completion date
01/01/2007

Eligibility

Key inclusion criteria
All confirmed myocardial infarction with either an ST elevation myocardial infarctions confirmed by raised CK and SHBD and Non ST elevation myocardial infarctions confirmed by a positive Troponin T of >0.1micrograms.L-1.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
6 patients in each arm

Key exclusion criteria
1. MI patients that do not fit the inclusion criteria
2. HAD Score at 12 weeks of below 8 and above 21 will be excluded from the study

Date of first enrolment
01/02/2004

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Hillingdon Hospital NHS Trust
Hillingdon

United Kingdom
UB8 3NN

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Hillingdon Hospital NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration